



TELEPHONE: 512/536-5201  
FACSIMILE: 512/536-5201

STEVEN L. HIGHLANDER  
PARTNER

INTERNET ADDRESS:  
SHIGHLANDER@FULBRIGHT.COM

DIRECT DIAL: 512/536-3184

## FULBRIGHT & JAWORSKI L.L.P.

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February 7, 2002

FILE: UTSC:684US

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Steven L. Highlander

Commissioner for Patents  
Washington, DC 20231

RE: *SN 10/010,763 "METHODS FOR DETECTING THE EFFICACY OF ANTICANCER TREATMENTS" – Isaiah J. Fidler and Corazon D. Bucana*  
(Client Reference: MDA00-053)

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references (A1-A3, C1-C30).

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10110590/SLH.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Steven L. Highlander  
Reg. No. 37,642

SLH/cmb

Encl: as noted

25122245.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Isaiah J. Fidler  
Corazon D. Bucana

Serial No.: 10/010,763

Filed: November 2, 2001

For: METHODS FOR DETECTING THE  
EFFICACY OF ANTICANCER  
TREATMENTS

Group Art Unit: 1645

Examiner: Unknown

Atty. Dkt. No.: UTSC:684US/SLH

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

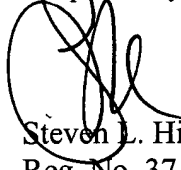
In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10110590/SLH.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Steven L. Highlander  
Reg. No. 37,642  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 474-5201

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Form PTO-1449 (modified)

Atty. Docket No.  
UTSC:684US/SLHSerial No.  
10/010,763

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant  
Isaiah J. Fidler  
Corazon D. BucanaFiling Date:  
November 2, 2001Group:  
1645U.S. Patent Documents  
See Page 1Foreign Patent Documents  
See Page 1Other Art  
See Page 1

## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	5,340,744	8/23/94	Lavker <i>et al.</i>	436	63	10/12/93
	A2	5,427,916	6/27/95	Gewirtz <i>et al.</i>	435	6	8/10/94
	A3	5,599,681	2/4/97	Epstein <i>et al.</i>	435	7.23	10/13/94

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Akiyama <i>et al.</i> , "Growth factor and growth factor receptor localization in the hair follicle bulge and associated tissue in human fetus," <i>J. Invest. Dermatol.</i> , 106(3):391-396, 1996.
	C2	Bergler <i>et al.</i> , "The expression of epidermal growth factor receptors in the oral mucosa of patients with oral cancer," <i>Arch. Otorhinolaryngol.</i> , 246(3):121-125, 1989.
	C3	Bergmann <i>et al.</i> , "Insulin-like growth factor I overexpression in human pancreatic cancer. evidence for autocrine and paracrine roles," <i>Cancer Res.</i> , 55:2007-2011, 1995.
	C4	Bruns <i>et al.</i> , "Blockade of the epidermal growth factor receptor signaling by a novel tyrosine kinase inhibitor leads to apoptosis of endothelial cells and therapy of human pancreatic carcinoma," <i>Cancer Res.</i> , 60:2926-2935, 2000.
	C5	Bruns <i>et al.</i> , "In vivo selection and characterization of metastatic variants from human pancreatic adenocarcinoma by using orthotopic implantation in nude mice," <i>Neoplasia</i> , 1:50-62, 1999.
	C6	Chan <i>et al.</i> , "A common human skin tumour is caused by activating mutations in $\beta$ -catenin," <i>Nat. Genet.</i> , 21:410-413, 1999.
	C7	Ciardiello <i>et al.</i> , "Antitumor activity of combined blockade of epidermal growth factor receptor and protein kinase A," <i>J. Nat'l Cancer Inst.</i> , 88:1770-1776, 1996.

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Form PTO-1449 (modified)

Atty. Docket No.  
UTSC:684US/SLHSerial No.  
10/010,763

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

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Applicant  
Isaiah J. Fidler  
Corazon D. BucanaFiling Date:  
November 2, 2001Group:  
1645U.S. Patent Documents  
See Page 1Foreign Patent Documents  
See Page 1Other Art  
See Page 1

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C8	Gill <i>et al.</i> , "Monoclonal anti-epidermal growth factor receptor antibodies which are inhibitors of epidermal growth factor binding and antagonists of epidermal growth factor binding and antagonists of epidermal growth factor-stimulated tyrosine protein kinase activity," <i>J. Biol. Chem.</i> , 259:7755-7760, 1984.
	C9	Green and Couchman, "Differences in human skin between the epidermal growth factor receptor distribution detected by EGF binding and monoclonal antibody recognition," <i>J. Invest. Dermatol.</i> , 85(3):239-245, 1985.
	C10	Green and Couchman, "Distribution of epidermal growth factor receptors in rat tissues during embryonic skin development, hair formation, and the adult hair growth cycle," <i>J. Invest. Dermatol.</i> , 83(2):118-123, 1984.
	C11	Green <i>et al.</i> , "Distribution and number of epidermal growth factor receptors in skin is related to epithelial cell growth," <i>Dev. Biol.</i> , 100:506-512, 1983.
	C12	Hansen <i>et al.</i> , "Genetically null mice reveal a central role for epidermal growth factor receptor in the differentiation of the hair follicle and normal hair development," <i>Am. J. Pathol.</i> , 150(6):1959-1975, 1997.
	C13	Harmon <i>et al.</i> , "Bisindolylmaleimide protein-kinase-C inhibitors delay the decline in DNA synthesis in mouse hair follicle organ cultures," <i>Skin Pharmacol.</i> , 10:71-78, 1997.
	C14	Korc <i>et al.</i> , "Overexpression of the epidermal growth factor receptor in human pancreatic cancer is associated with concomitant increases in the levels of epidermal growth factor and transforming growth factor alpha," <i>J. Clin. Invest.</i> , 90:1352-1360, 1993.
	C15	Lokshin <i>et al.</i> , "Mechanisms of growth stimulation by suramin in non-small-cell lung cancer cell lines," <i>Cancer Chemother Pharmacol.</i> , 43:341-347, 1999.
	C16	Luetteke <i>et al.</i> , "The mouse waved-2 pheontype results from a point mutation in the EGF receptor tyrosine kinase," <i>Genes Dev.</i> , 8:399-413, 1994.
	C17	Maiorano and Favia, "Expression of phosphotyrosine in squamous cell carcinoma of the oral mucosa. Preliminary study," <i>Boll. Soc. Ital. Biol. Sper.</i> , 71(5-6):157-162, 1995.
	C18	Maiorano <i>et al.</i> , "Prognostic implications of epidermal growth factor receptor immunoreactivity in squamous cell carcinoma of the oral mucosa," <i>J. Pathol.</i> , 185:167-174, 1998.

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Form PTO-1449 (modified)		Atty. Docket No. UTSC:684US/SLH	Serial No. 10/010,763
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Isaiah J. Fidler Corazon D. Bucana	
		Filing Date: November 2, 2001	Group: 1645
U.S. Patent Documents See Page 1	Foreign Patent Documents See Page 1	Other Art See Page 1	

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## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C19	Murillas <i>et al.</i> , "Expression of a dominant negative mutant of epidermal growth factor receptor in the epidermis of transgenic mice elicits striking alterations in hair follicle development and skin structure," <i>EMBO J.</i> , 14(21):5216-5223, 1995.
	C20	Nameda <i>et al.</i> , "Endotoxin-induced L-arginine pathway produces nitric oxide and modulates the Ca <sup>2+</sup> activated K <sup>+</sup> channel in cultured human dermal papilla cells," <i>J. Invest Dermatol.</i> , 106:342-345, 1996.
	C21	Saleh <i>et al.</i> , "Combined modality therapy of A431 human epidermoid cancer using anti-EGFr antibody C225 and radiation," <i>Cancer Biother. Radiopharm.</i> , 14:451-463, 1999.
	C22	Smythe <i>et al.</i> , "The activity of HMG-CoA reductase and acetyl-CoA carboxylase in human apocrine sweat glands, sebaceous glands, and hair follicles is regulated by phosphorylation and by exogenous cholesterol," <i>J. Invest. Dermatol.</i> , 111:139-148, 1998.
	C23	van Oijen <i>et al.</i> , "Increased expression of epidermal growth factor receptor in normal epithelium adjacent to head and neck carcinomas independent of tobacco and alcohol abuse," <i>Oral Dis.</i> , 4(1):4-8, 1998.
	C24	Wagner <i>et al.</i> , "Suppression of fibroblast growth factor receptor signaling inhibits pancreatic cancer growth in vitro and in vivo," <i>Gastroenterology</i> , 114:798-807, 1998.
	C25	Wang <i>et al.</i> , "Effects of in vivo treatments of nicotine and benzo[a]pyrene on the epidermal growth factor receptor in hamster buccal pouch," <i>Toxicology</i> , 107:31-38, 1996.
	C26	Wang <i>et al.</i> , "Identification of epidermal growth factor receptor in human buccal mucosa," <i>Arch. Oral Biol.</i> , 35(10):823-828, 1990.
	C27	Whitcomb <i>et al.</i> , "Immunohistochemical mapping of epidermal growth-factor receptors in normal human oral soft tissue," <i>Arch. Oral Biol.</i> , 38(9):823-826, 1993.
	C28	Yamada <i>et al.</i> , "Evaluation of epidermal growth factor receptor in squamous cell carcinoma of the oral cavity," <i>Oral. Surg. Oral Med. Oral Pathol.</i> , 73:67-70, 1992.
	C29	Yamanaka <i>et al.</i> , "Coexpression of epidermal growth factor receptor and ligands in human pancreatic cancer is associated with enhanced tumor aggressiveness," <i>Anticancer Res.</i> , 13:565-569, 1993.
	C30	Yamanaka <i>et al.</i> , "Overexpression of HER2/neu oncogene in human pancreatic carcinoma," <i>Hum. Pathol.</i> , 24:1127-1134, 1993.

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